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CANNON BUILDING 861 SILVER LAKE BLVD., SUITE 203 DOVER, DELAWARE 19904-2467

STATE OF DELAWARE DEPARTMENT OF STATE

DIVISION OF PROFESSIONAL REGULATION

FAX: (302) 739-2711 WEBSITE: WWW.DPR.DELAWARE.GOV

TELEPHONE: (302) 744-4501

APPLICATION FOR IN-STATE PHARMACY PERMIT

No person shall operate any pharmacy within this State without first having obtained a permit to do so from the Board of Pharmacy.

This application must be accompanied by a non-refundable, pro-rated fee. Please refer to the Fee Schedule at www.dpr.delaware.gov for the correct fee.

	ss of Pharmacy:(Include street and number)	
City aı	nd Zip:Delaware, from October 1,	to September 30, 20
Busine	ess Telephone:	(include area code
edera	al (DEA) Controlled Substances Registration Number:	
State (CSA) Controlled Substance Registration Number:	
	Name or Title under which the Pharmacy is conducted:	
2.	If corporation, give date of charter and names and titles of principal officers:	
3.	If partnership, give names and titles of all active partners:	
		
	-	
l.	If individually owned, give name and address of owner:	
	if individually owned, give hance and address of owner.	

5.	Business site hours of operation:	Weekdays		A.M. to	P.M.
		Weekends	Saturday	A.M. to	P.M.
		Weekends		A.M. to	
				A.M. to	
6.	Pharmacy Phone Number (if available	e)			
7.	Pharmacy Department hours:	Weekdays		A.M. to	P.M.
		Weekends	Saturday	A.M. to	P.M.
		Weekends		A.M. to	
			Holidays	A.M. to	P.M.
8.	Names and Certificate Numbers of Re	egistered Pharmacists	::		
	Staff Pharmacists:	License #	St	taff Pharmacists:	License #
			<u> </u>		
9.	Names of all unregistered employees			Initial date of employme	nt
	-				
	-				

The following are statutory and regulatory requirements associated with your pharmacy application.

All statutes and regulations related to pharmacy requirements may be found in full at www.dpr.delaware.gov

- 10. 24 <u>Del. C.</u> §2526 Requirements for an Issuance of Permit: In determining if a permit should be issued, the Board shall consider the following factors:
 - 1. The Pharmacy will be conducted in full compliance with the law and with rules and regulations of the Board.
 - 2. The Pharmacy will be managed by a pharmacist-in-charge properly registered in the State who can only serve in that position for one pharmacy.
 - 3. The location and appointments of the pharmacy are such that it can be operated and maintained without endangering public health and safety. In determining a danger to the public health or safety, the Board shall consider the following factors:
 - a. Applicant, principal or anyone having controlling ownership interest is of good moral character.
 - b. Any conviction of applicant, principal or anyone having controlling ownership interest under federal or any state's law for deceptive business practices or violations of drug law.
 - c. Any actions by a regulatory agency against the permit holder or applicant, principal or anyone having controlling ownership interest for violations of its statutes and regulations.
 - 4. The application shall contain the name of a pharmacist-in-charge who will assume the responsibility in writing for compliance with the pharmacy, controlled substances and other applicable statutes and regulations.

- 11. 24 Del. C. §2531 Availability of Permit; expiration date; transfer. Permits issued under the provisions of this subchapter shall:
 - 1. Be available on site for inspection by authorized persons.
 - 2. Expire on the last day of September biennially (even years).
 - 3. Not be transferable.
- 12. 24 <u>Del. C.</u> §2532 Equipment Requirements: (a) The Board shall prescribe the minimum of the professional and technical equipment and texts that a pharmacy shall at all time possess. Regulation 3.3 requires each pharmacy to have the following equipment and to maintain a library of the latest edition and supplements of current reference sources (either hard copy or electronically accessible appropriate to the practice and to the care of the patient served).

 $State\ how\ this\ information\ will\ be\ obtained.\ (e.g.\ internet\ FDA\ website,\ current\ text\ with\ name,\ edition/year,\ etc.)$

- 13. 24 Del. C. §2534 (1) Prescription Department must occupy at least 250 square feet of floor space excluding a storeroom.
 - (2) The prescription counter must be at least 18 inches wide with four linear feet kept clear and free of all merchandise for each pharmacist working concurrently.
 - (3) The aisle behind the counter must be at least 30 inches wide and shall be kept free of obstruction at all times.
- 14. 24 <u>Del. C.</u> §2553 Substitution of drugs. The drug is therapeutically equivalent according to FDA "Approved Prescription Drug Products with Therapeutic Equivalents Evaluations" and its supplements.
- 15. 24 <u>Del. C.</u> §2533 Prescriptions; Preservation of record: Every proprietor or manager of a pharmacy shall keep a suitable book or file, in which shall be preserved for a period of not less than three (3) years the original of every prescription compounded or dispensed at such pharmacy. Such book or file of original prescriptions shall at all times be open to inspection by duly authorized agents of the Board and the Department of Health and Social Services.
- 16. 24 Del. C. §2534 (b) Security: No one but a pharmacist shall be able to unlock and lock the prescription department.
- 17. 24 <u>Del. C.</u> §2534(c) A sign with letters not less than 3/4" in height in the vicinity of the prescription department visible to the public which shows the names of the pharmacists employed at that pharmacy or the name of the pharmacist on duty.
- 18. Regulation 3 Physical Facilities.
 - 3.4 Have sufficient size, space, sanitation, environmental control for adequate distribution, dispensing and storage of drugs and devices. Such facilities shall include:
 - 3.4.1. A dispensing area of adequate size and space for proper compounding, dispensing and storage of drugs and devices, to ensure the safety and well being of the public and pharmacy personnel.
 - 3.4.2 Sufficient environmental control, i.e. lighting, ventilation, heating and cooling to maintain the integrity of drugs and devices. The area in which drugs and devices are stored shall be accurately monitored using control devices to maintain room temperature between 59° and 86° Fahrenheit.
 - 3.4.3 The pharmacy department or prescription area must contain a sink with hot and cold running water. It must be large enough to accommodate the equipment required by the Board so that the utensils can be properly washed and sanitized.
 - 3.4.4 Suitable refrigeration with appropriate monitoring device. Refrigerators and freezers (where required) will be maintained at the USP/NF range:

Refrigerator - 36 degrees to 46 degrees Fahrenheit

Freezer - minus 4 degrees to plus 14 degrees Fahrenheit.

	Patient Profile Requ	irements: (Every item must	t be checked fo	r compliance)	
	(5.7.1.2.1) Family name and first name of the person for whom the medication intended (the patient);				
	(5.7.1.2.2) Address of patient and phone number (or location in institution);				
(5.7.1.2.3) The patient's age or date of birth, and gender;					
	(5.7.1.2.4) The original	inal date the medication is d	ispensed pursu	ant to the receipt of the	prescription;
	(5.7.1.2.5) Number	or designation for prescript	ion;		
	(5.7.1.2.6) Prescriber's name;				
	(5.7.1.2.7) Name, strength, quantity, directions and refill information of drug dispensed. Appropriate directions must also be present if medication is for patients in institutions;				
	(5.7.1.2.8) Initials of dispensing pharmacist and date of dispensing medication as a refill if said initials and date are not recorded on original prescription;				
	(5.7.1.2.9) If patient refuses to give all or part of the required information, the pharmacist shall indicate and initial in the appropriate area;				
	(5.7.1.2.10) Pharma drug.	cist comments relevant to	the patient's	drug therapy, includi	ing any other information peculiar to the specific patient or
	(5.7.3) The pharmacist or pharmacy intern under the direct supervision of a pharmacist shall attempt to ascertain and shall record any allergies and idiosyncrasies of the patient and any chronic disease states and frequently used over-the-counter medication as communicated to the pharmacist by the patient. If the answer is none, this must be indicated on the profile.				
ha co	rofile record before di armful reaction or int onsultation with the pl	spensing the medication to eraction, the pharmacist shapsician. e record must be maintained	determine the all take approp	possibility of a harmful priate action to avoid on	e direct supervision of a pharmacist must examine the patient's l drug interaction or reaction. Upon recognizing a potential r minimize the problem, which shall, if necessary, include ar from the date of the last entry in the profile record
20.	I understand that I Federal laws.	am responsible for conduc	cting and man	aging the prescription	department in compliance with applicable State and
	Pharmacist-in-Char	ge:			Pharmacist License #
			(Signatu		
21.	•	cers/owners or pharmacists		ricted, fined, or had a lic	cense revoked for a violation of pharmacy or drug laws?
	Yes		No		
22.	Have any of the offi application denied?	cers, owners, or pharmacis	ts ever applied	l for a pharmacy permi	it or controlled substances registration in any State and had the
	Yes		No		
23.	Have any of the office	cers, owners, or pharmacists	been convicte	d of a felony or are they	presently charged with the commission of a felony?
	Yes		No		

19.

Regulation 5.0 Dispensing

If the answer to any of the above questions is yes, explain in detail. (Use se	eparate sheet, if necessary.)
24. List the name, address, date of birth and social security number	r of each officer, owner and pharmacist:
	to receive your permit. A <u>complete</u> application is one that includes all required rd meeting, pharmacy license applications must be submitted at least 15 days prior to meetings may be found at our website www.dpr.delaware.gov
Applications that are not <u>complete</u> within six (6) months of filing may be before disposing of an abandoned application.	considered abandoned and discarded. The Board office will attempt to notify you
I hereby swear or affirm that all the foregoing statements are correct and	do hereby agree to abide by the Pharmacy laws of the State of Delaware.
	Signature
(SEAL)	Subscribed and sworn to before me this
	NOTARY PUBLIC

(This permit will expire on the last day of September biennially of even years. Permits are not transferable.)